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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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STEPHEN DONOVAN
ALLERGAN, INC.
T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on February 10, 2010 is acknowledged. Claims 1 and 12 have been amended. Claims 22-24 have been canceled. Claims 1-6, 8-10 and 12-21 are currently pending and under examination.

Claim Objections

2. Claims 10 and 12 are objected to because of the following informalities: Claim 10 requires a space between "claim" and "1". Claim 12 requires a comma in place of the period after "thereby treating the skin disorder". Appropriate correction is required.

Objections Withdrawn

3. In view of Applicant's amendment, the objection to claims 22-24 for depending on rejected claim 12 is withdrawn. The cancellation of claims 22-24 renders the objection to said claims moot.

Rejections Withdrawn

4. In view of Applicant's amendments the rejection of claims 1-6, 8-10 and 12-21 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf, accessed on March 22, 2007) is withdrawn.

New grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite "...with a hollow bore" and "....wherein the administration of said liquid solution comprising botulinum toxin does not follow the administration of a first drug within said session". These phrases do not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Applicant points to the specification as filed for support for said amendment, however, the specification does not disclose anything regarding said amendments.

To overcome this rejection Applicant must specifically point out the support for this limitation or cancel the new matter from the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 12-16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf; accessed on March 22, 2007), and further in view of What is Hyperkeratosis (Health A-Z- www.everydayhealth.com; accessed 5/19/10) and Seborrheic Keratosis (eMedicine Dermatology- www.emedicine.medscape.com; accessed 5/19/10).

The rejected claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a typical mole, a dysplastic mole, a pyogenic granuloma or a seborrheic keratose; and wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

Kwon discloses a method of administering a safe and effective amount of botulinum toxin, which, as evidenced by Allergan, is botulinum toxin type A, for treating

lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions, actinic keratoses and hard hyperkeratotic skin, which is often found on the face, arms, legs or feet (see page 6, paragraph 0077). Kwon discloses administering the botulinum toxin via a patch (topical). Kwon discloses that a design of an SSP patch includes an array of perforators (i.e. needles, blades or other perforators, which meets the limitation of intradermal or subdermal injection) that is porous. Moreover, Kwon discloses that at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution. Kwon discloses that the design is ideal for potent drug delivery for administering small doses systemically (see page 5, paragraph 0049). The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (see page 21), inherently Kwon has administered a therapeutically effective amount of botulinum toxin and therefore necessarily administers an amount of botulinum toxin which is less than the amount used to paralyze a muscle. With regard to claims 16, 20 and 21, due to the mode of action of botulinum toxin its administration would necessarily reduce a pain and/or inflammation associated with the skin disorder as well as reduces the size of said disorder.

Kwon does not specifically disclose that the skin disorder is a seborrheic keratose.

Everydayhealth.com discloses that hyperkeratosis is a thickening of the outer layer of the skin and causes calluses and corns. Examples of hyperkeratosis include seborrheic keratoses (see page 1 of 2).

Moreover, emedcine.com discloses that seborrheic keratoses can be an annoyance, they can catch onto clothing and become irritated, they can itch, grow and bleed; and they are often unattractive and serve as negative psychological connotations (see page 2 of 26).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kwon by administering botulinum toxin to specifically target and treat seborrheic keratoses because they can be an annoyance, they can catch onto clothing and become irritated, they can itch, grow and bleed, and they are often unattractive. One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for treating a skin disorder comprising a seborrheic keratose because Kwon discloses treatment of lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and actinic keratoses and hard hyperkeratotic skin using botulinum toxin and seborrheic keratoses is one of the few types of hyperkeratotic skin conditions.

The claim would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Conclusion

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

LJT
5/19/10